SEP 1 1 2001

K011403

510(k) Summary

Submitted on behalf of:

Company Name: **Orthogen Corporation**
Address: **530 Morris Avenue, Ste 204**
Springfield, NJ 07081
Telephone: **973-467-2404**
Fax: **973-467-1218**

by: President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
Telephone: 715-549-6035
Fax: 715-549-5380

CONTACT PERSON: Elaine Duncan, M.S.M.E., RAC

DATE PREPARED: **May 3, 2001**

TRADE NAME: **SURGI*PLASTER*™ Calcium Sulfate Hemihydrate**

COMMON NAME: **Bone filling augmentation material**

SUBSTANTIALLY EQUIVALENT TO:
CAPSET Calcium Sulfate Bone Substitute K 955096and Fortoss- CEMA K993238

DESCRIPTION of the DEVICE: **SURGI*PLASTER*™** Calcium Sulfate Hemihydrate, supplied by CLASSimplant, s.r.l., distributed by Orthogen Corporation, is a medical grade calcium sulfate hemihydrate powder. **SURGI*PLASTER*** is designed to set-up in vivo and may be used either alone or mixed with DFDBA (demineralized freeze-dried bone allograft) or autogenous bone in bone regenerative procedures. It is mixed with small amounts of regular setting solution to produce a putty-like paste and it is applied on bone defects in overlapping layers. Each layer is then compressed with a small square of sterile gauze. The last layer is set using a small square of sterile gauze soaked in the fast setting solution. With time, the resorbing, set **SURGI*PLASTER*** dissolves and recedes leaving behind bioactive calcium phosphate deposits that have been found to stimulate bone in-growth.

INDICATIONS FOR USE:
SURGI*PLASTER*™ Calcium Sulfate Hemihydrate is indicated for use in the following ways; by itself in bone regenerative techniques; mixed with other suitable bone filling agents to prevent particle migration in an osseous defect; and, to provide a resorbable barrier over other bone graft material

SUMMARY of TESTING:
Orthogen Corporation has 1) tested the chemical composition of **SURGI*PLASTER*™** Calcium Sulfate Hemihydrate by an independent laboratory to a recognized test method (USP NSF 18) and reported the results in this submission; and, 2) has provided extensive literature articles documenting the use of calcium sulfate as a bone augmentation material, including an extensive literature reference. Therefore this material has been qualified as biocompatible and safe for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 1 2001

Orthogen Corporation
C/O Ms. Elaine Duncan
Paladin Medical, Incorporated
P.O. Box 560
Stillwater, Minnesota 55082

Re: K011403
Trade/Device Name: Surgiplaster Calcium Sulfate Hemihydrate
Regulation Number: 872.3640
Regulation Name: Bone Filing Augmentation Material
Regulatory Class: Unclassified
Product Code: LYC
Dated: August 3, 2001
Received: August 6, 2001

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K011403

Device Name: SURGI*PLASTER*™ Calcium Sulfate Hemihydrate

Indications for Use:

SURGI*PLASTER*™ Calcium Sulfate Hemihydrate is indicated for use in the following ways:

- by itself in bone regenerative techniques
- mixed with other suitable bone filling agents to prevent particle migration in an osseous defect
- to provide a resorbable barrier over other bone graft material

(Please Do Not Write Below This Line-Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over -The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011403